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EXAMINER	
NGUYEN, TRAN N	

ART UNIT	PAPER NUMBER
2197	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/849,252	ABRAHAM-FUCHS ET AL.	
	Examiner	Art Unit	
	Tran N. Nguyen	2197	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 May 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner has conducted a complete, thorough, and best-effort examination even though **the application is replete with errors.** Examiner respectfully requests and strongly urges Applicant to review the application in its entirety in view of the issues raised herein.

Priority

Acknowledgment is made of Applicant's claim for foreign priority based on an application filed in Germany on May 20, 2003. It is noted, however, that **Applicant has not filed a certified English translation** of the **DE 103 22 687.7** application as required by 35 U.S.C. 119(b). Correction is required.

Examiner respectfully reminds Applicant that **such English translation should be filed together with a statement that the translation of the certified copy is accurate.** This is necessary to ensure that no new matter is introduced in translation.

Drawings

The drawings are objected to because they are replete with errors. Examiner respectfully requests and strongly urges Applicant to review all drawings in their entirety. Objections to the drawings include, but are not limited to the following:

- The unlabeled rectangular boxes shown in all figures should be provided with **descriptive text labels.**

- The same structural entity is being assigned different terminology throughout the application. Examples of this error include, but are not limited to:
  - Data records D and therapeutic advice items 3 [0036].
  - Data records D and therapeutic information items 5 [0037].
- Examiner requires Applicant to amend the drawings to properly show the data structure of the therapeutic advice items as they relate to data records.
- Referencing should be illustrated by means of pointers linking the inputs and outputs of the therapeutic advice item to other therapeutic advice items.
- Deep and shallow copying should be **clearly inferable** from the drawings.
- Recursive structures should be illustrated as such.
- **Proper numbering** of elements and sub-elements (e.g. element A containing a plurality of sub-elements A_1, A_2, ..., A_i) should be employed.
- Different instantiations of the structure used to illustrate genus and species variations of the structure should be **properly labeled with non-conflicting numbers and terminology** as to avoid confusion.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by Examiner, Applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Abstract

The abstract is objected to because it is replete with errors. Examiner respectfully requests and strongly urges Applicant to review the abstract in its entirety in view of the issues raised herein. Objections to the abstract include, but are not limited to the following:

- It is not possible to ascertain the scope of the technical disclosure from the contents of the abstract. The abstract **should include the major steps of the process** as described in the technical disclosure. The abstract in current form does not concisely describe the invention.
- With respect to the word "is" in the phrase "A method *is* for ..." (line 1), please consider removing "is" for clarity.

Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

(1) if a machine or apparatus, its organization and operation;

(2) if an article, its method of making;

(3) if a chemical compound, its identity and use;

(4) if a mixture, its ingredients;

(5) **if a process, the steps**.

Extensive mechanical and design details of apparatus should not be given.

Applicant is also reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. **The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.**

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Specification

A **substitute specification in proper idiomatic English** and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive

characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification include, but are not limited to:

It is insolubly ambiguous what Applicant considers to be a "therapeutic advice item", and no meaningful interpretation can be inferred from Applicant's disclosure. It is especially unclear what the relationship between a data record and a therapeutic advice item is based upon Applicant's specification language and drawings. There exist multiple and conflicting definitions as such. Examples of inconsistent terminology include, but are not limited to:

- "The invention generally relates to a method and an apparatus for processing and outputting a version change for a data record which **includes** medical therapeutic advice items" [0002]. This sentence implies that a data record may contain a plurality of therapeutic advice items.

- "The data record is itself **referred** to as a therapeutic advice item below for short" [0002]. This sentence implies that a therapeutic advice item is a data record.
- "The data record may include... data items, that is to say therapeutic advice items,..." [0002]. This sentence implies that therapeutic advice items are data items, and that a data record may contain a plurality of therapeutic advice items.
- "Guidelines are diagnostic and/or therapeutic recommendations for action and decisions (subsequently **referred** to as therapeutic advice items in general and in summary) to the doctor which have been drawn up in a broad consensus by *superordinate* and generally recognized committees in the medical profession" [0003]. It is **insolubly ambiguous to what the parenthetical expression refers**: decisions, action, action and decisions, diagnostic and/or therapeutic recommendations, diagnostic and/or therapeutic recommendations for action, diagnostic and/or therapeutic recommendation for action and decisions, guidelines, etc. Nonetheless, none of the aforementioned entities, referred to as therapeutic advice items, is equivalent to a data record (data records being therapeutic advice items according to Applicant's disclosure). Therefore, **Applicant's definition of a data record, a therapeutic advice item, and the equivalence thereof are incorrect.**

The term "data record", first appearing in paragraph [0002] and referred to throughout the application, is ambiguous. Since Applicant's explicit definition in is ambiguous, it is especially unclear if a "data record" refers to a single element of a collection of information (a row in a table), as is standard in database terminology, or the complete collection of all data about a patient as comprising that patient's medical record, as is standard in medical terminology.

Additional errors exist in the disclosure. **Examiner requires Applicant to address these inconsistencies as they preclude a thorough examination of the instant pending application.**

For examination purposes, the following assumptions have been made in a best-effort attempt to comprehend Applicant's disclosure:

- A "therapeutic advice item" is interpreted to mean **a single embodiment of data, software, and associated expert rules adapted for inputting, processing, storing, and outputting patient data in line with therapeutic guidelines.**
- The term "data record" has been given its **ordinary meaning in the medical industry**.
- A "therapeutic information item" is interpreted to mean **patient data**.
- The term "order feature" has been interpreted to mean a **unique identifier**.

- The term "release attribute" is interpreted to mean **development stage** (pre-alpha, alpha, beta, etc).
- The term "activation attribute" is interpreted to mean **usability flag**.
- The terms "use attribute" and "use advice item" are interpreted to mean the **mapping between therapeutic advice items and therapeutic information items**.

The disclosure is objected to because of the following informalities:

- "The invention generally relates to a method for processing referencing therapeutic advice items, particularly data records **which** include "medical guidelines" [0002]. It is unclear to what the qualifier "which" refers.
- "Naturally, such therapeutic advice items need to be continually brought into line with the latest level of knowledge and are thus subject to continual, **if normally long or medium term**, change" [0004]. It is unclear what the phrase "if normally long or medium term" means.
- "An embodiment of the invention is therefore based on an **object** of specifying a method for..." [0007]. It is unclear what the specified object is.
- The phrase "a particular clinical **picture**" [0019] is unclear. Examiner respectfully suggests Applicant to revise the phrase "clinical picture" to industry standard terminology, such as "clinical scenario", etc.

- Examiner respectfully requests Applicant to number the lines on each page (including the abstract), in addition to the existing paragraph numbering, to facilitate the examination process.

Additional errors exist in the disclosure. Appropriate correction is required.

Claim Objections

Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant's recitation of referencing data records according to the assigned order feature does not further limit the method steps. Additionally, it is inherent that a unique order feature be used to reference the associated data record.

Claim 26 is also objected to under the same rationale.

Applicant is advised that should claims 1, 17, 2, 3, 4, 5, 24, 31, and 32 be found allowable, claims 18, 19, 20, 21, 22, 23, 25, 35, and 36, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 31-36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The language of the claims raise a question as whether the claims are directed merely to an abstract idea that is not a statutory category of invention (process, machine, manufacture or composition of matter) which would result in a practical application, producing a concrete, useful, and tangible result.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. All pending claims are replete with errors. Again, Examiner respectfully urges Applicant to consider the **use of proper idiomatic English**. Applicant's attention is directed to instances when **word choice, sentence structure, and punctuation render the claim indefinite**. It is therefore **not possible to fully ascertain Applicant's claimed invention from Applicant's claim recitation**.

With respect to independent claim 1, examples where claim 1 fails to particularly point out and distinctly claim the invention include, but are not limited to, the following:

- The functionality of a therapeutic advice item.
- The functionality of a data record.
- The steps involved in the method.

All claims dependent thereon fail to remedy these deficiencies, and are also rendered indefinite.

Independent claims 6, 18, 29, 30, and all claims dependent thereon are also rejected under the same rationale.

With respect to claim 5, the term "therapeutic advice item" is ambiguous because no such item exists in the second database in the scope of claim 5 or parent claim 1.

With respect to claim 16, the term "therapeutic information item" lacks antecedent basis because no such item exists in the scope of claim 16 or parent claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-36 are rejected under 35 U.S.C. 102(b) as being unpatentable under U.S. Patent 5,307,262 issued to Ertel (hereafter referred to as Ertel '262).

With respect to claim 1, the structural limitation present in the preamble and throughout the claim is given no limiting effect on the method steps. For examination purposes, claim 1 is interpreted to recite a method comprising of a single step of assigning data records a version identifier.

With respect to claims 1, 16, 24, 6, and 26, Ertel '262 teaches a record containing an "identifier of [DRG] grouper version used "(column 13, line 64), wherein a DRG grouper is a program that assigns diagnosis-related groupings, i.e. therapeutic advice items, to patients (column 1, lines 16-22 and column 8, lines 53-57). Additionally, each patient record is assigned a unique patient identifier (column 9, line 28).

With respect to claims 2 and 9, Ertel '262 teaches that a DRG grouper further comprises of "diagnosis and procedure code tables, DRG assignment number tables, and other subsidiary files including one that contains **special attributes associated with diagnosis and procedures**" (column 11, lines 20-24). According to Ertel '262's teachings, date-appropriate versions of the DRG grouper are called as needed (column 11, lines 16-20).

Therefore, it is inherent that a DRG grouper implementing version control would have a development stage and usability flag attributes, as is typical with systems implementing version control.

With respect to claims 3, 17, and 10, Ertel '262 further teaches that DRG's cluster patients to economically homogenous groups (column 1, lines 19-22). "DRG's are assigned... based upon "case complexity" as conveyed through the configuration of diagnoses reported and/or procedures performed during the course of the hospital stay" (column 1, lines 22-26).

Therefore, since DRG's are mapped to patient data, it is possible to find patients who are grouped in a particular DRG, as well as to find the DRG('s) to which a particular patient is grouped. Ertel '262's teachings provide the ability to store the use attribute of the DRG.

With respect to claims 4 and 11, Ertel '262 further teaches that "the DRG grouper program... is updated yearly according to Federal specifications. Multiple versions of the DRG Grouper can be accessed..." (column 11, lines 8-14). Ertel '262 also teaches "to invoke an automatic selection among several groupers on the basis of matching the case discharge date against the implementation date range appropriate to each grouper" (column 9, lines 56-62).

Therefore, each DRG includes a date used to map to patient data.

With respect to claim 5, Ertel '262 further teaches that hospital stay data, discharge data, and clinical data are archived and accumulated in the archival patient records file (column 16, lines 3-9). The start date of a therapeutic treatment falls under these categories, and has been anticipated under Ertel '262's teachings.

With respect to claims 31, 32, 33, and 34, Ertel '262 further teaches a program of instructions for detecting, analyzing and classifying patient data; and a system memory for storing the program of instructions (claim 40).

With respect to claims 7, 27, and 8, Ertel '262 further teaches that a change in DRG guidelines generates a case-by-case list of changes in DRG assignments, and an overall summary of the financial impact of the entire review process (column 15, lines 38-49). According to Ertel '262's teachings, the report outlines those DRG's affected by the change as well as those patient data affected by such a change (Tables 6-8).

With respect to claims 28 and 12, Ertel '262 further teaches "to invoke an automatic selection among several groupers on the basis of matching the case discharge date against the implementation date range appropriate to each grouper" (column 9, lines 56-62). Therefore, the system according to Ertel '262's teachings maintains the mapping between patient records and obsolete DRG's based upon the discharge date of the patient.

With respect to claim 13, Ertel '262 further teaches the use of date-appropriate versions for DRG groupers (column 11, lines 8-13). Ertel '262 also teaches that the DRG grouper may also utilize a variety of data files to describe the DRG (column 11, lines 1-3).

With respect to claims 14 and 15, Ertel '262 further teaches "to invoke an automatic selection among several groupers on the basis of matching the case discharge date against the implementation date range appropriate to each grouper" (column 9, lines 56-62). This expert rule maps patient data records to the appropriate version of the DRG based upon the patient's discharge date.

With respect to claims 18, 19, 20, 21, 22, 23, 25, 35, and 36, the limitations of claims 1, 17, 2, 3, 4, 5, 24, 31, and 32 substantially encompass the limitations of claims 18, 19, 20, 21, 22, 23, 25, 35, and 36, respectively; i.e. they are of substantially the same scope. Therefore, claims 18, 19, 20, 21, 22, 23, 25, 35, and 36 are rejected for at least the same reasons as claims 1, 17, 2, 3, 4, 5, 24, 31, and 32.

Claims 29 and 30 are also rejected under the same rational with respect to claims 6 and 1, respectively.

Conclusion

Applicant's cited references have been considered; however, portions of foreign references not in English have not been considered. Only the English abstract of such references, if available, have been considered.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following reference(s) are cited but not applied:

1. U.S. Patent 5,508,912 issued to Schneiderman (hereafter referred to as Schneiderman '912). Schneiderman '912 teaches "using sets of clinical criteria including diagnostic category for specific record selection" (abstract and figure 8). Although not claimed, this functionality is recited by Applicant [0010].
2. U.S. Patent 5,924,074 issued to Evans (hereafter referred to as Evans '074). Evans '074 teaches "a method of managing a patient data repository having a cache and a data archive, comprising the steps of monitoring a status of data within the cache, and moving the data to the data archive when the status exceeds a threshold" (column 3, lines 31-35). Although not claimed, this functionality is recited by Applicant [0020].

Even if the claims were amended to an allowable state, the specification, drawings, and abstract are replete with errors, and would prevent timely and favorable

action for Applicant. Therefore, **Examiner respectfully requests and strongly urges Applicant to reconsider the application in its entirety.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran N. Nguyen whose telephone number is (571) 270-1310. The examiner can normally be reached on Monday - Friday, 7:0 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 274-1279. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tran N Nguyen
Examiner
Art Unit 2197

TN
9/26/2006

GARY JACKSON
SUPERVISORY PATENT EXAMINER